
Chapter 3

Identification and Resolution of Risk Assessment Issues

Determining the risks associated with pollutants in biosolids was a challenging process. Numerous factors had to be considered, many of which had not been fully explored previously. This chapter presents some of the key issues raised during the risk assessment process for biosolids and discusses how EPA resolved them. These issues are summarized in Table 9 and addressed in more detail throughout this chapter. The large letters to the left of each section heading in the text and in the left-hand column of Table 9 refer to the same risk assessment steps discussed in Table 1 in Chapter 2 and indicate when in the risk assessment process the issue was raised. Not all letters are shown because not all of the risk assessment steps discussed in Chapter 2 involved issues that required further resolution.

Step H Evaluation of Iron and Fluoride

Although the initial biosolids hazard index and ranking process (described in Chapter 2) identified both iron and fluoride as potentially toxic, EPA decided not to evaluate these two pollutants in the risk assessments for biosolids. EPA made this decision because toxic effects have only been observed under atypical conditions—in experiments with unusually high concentrations of iron and fluoride and single high volume applications of biosolids.

For example, cattle in which iron toxicity resulted were grazed on land to which, in an experiment, high iron content biosolids were land applied a day before grazing. These cattle received no supplemental feed and were continually rotated to new fields week after week immediately after the fields had been treated with high iron-content liquid biosolids.

Such an occurrence of elevated iron toxicity in cattle is highly unlikely other than in a similar experimental setting. The Part 503 rule requires at least a 30-day waiting period after application of Class B biosolids (those meeting certain pathogen reduction requirements) before allowing grazing. Possibly, Class A biosolids (virtually pathogen free) could be applied just before grazing; however, Class A biosolids are usually in a dry state and initially do not tend to stick to the forage, as do liquid Class B biosolids. Also, it is highly unlikely that biosolids in any form would continue to be applied week after week to pastures immediately before cattle graze.

Table 9
Issues Raised During the Biosolids Risk Assessment Process

Issue Raised During	Issue	Resolution of Issue
<i>Step E</i> Profile assessment	Retain or drop ocean disposal	Dropped—policy decision because of Ocean Disposal Ban Act
<i>Step H</i> Risk assessments for proposed rule	Drop iron and fluoride, which had high hazard indices	Iron is ubiquitous and an essential element; two studies showing high levels (Fe and F) considered to be unrepresentative; iron and fluoride not regulated
<i>Step J</i> Expert reviews	(1) Target organism	Replaced most exposed individual with highly exposed individual
	(2) Use of $1 \times 10^{-4}, -5, \text{ or } -6$ cancer risk level	Used 1×10^{-4} for all use or disposal practices (policy decision)
	(3) Salt/pot vs. biosolids/pot vs. field data	Used field data to accurately reflect biosolids pollutant concentrations in plants because salt data greatly overestimate actual uptake
	(4) Megaeater model	Replaced with better data and model
	(5) Drop organics from Part 503 rule	Policy decision—NSSS showed organics not present in sufficiently high levels in biosolids to exceed risk-based limits; infrequently detected; or no longer used or manufactured for use in the United States
<i>Step L</i> NSSS results, rule changes	Add concept for land application of biosolids containing low pollutant levels that require less regulatory control. If such biosolids meet pollutant concentration limits and certain pathogen and vector attraction reduction requirements, they would be minimally regulated	“Clean” biosolids concept shown to be viable by risk assessment for low pollutant concentrations; field data confirmed that land-applied biosolids containing low pollutant levels have no observed adverse effects on public health and the environment; NOAEL biosolids concept included in final Part 503 rule
<i>Step N</i> Internal EPA review	(1) Lead risk evaluation not properly conducted	Explained how animal data were used to show no impact on body burden; used EPA IEUBK model; risk management decision to use 300 ppm from animal data vs. 500 ppm from IEUBK model as land application pollutant concentration limit
	(2) Whether biosolids binding of metals is long-term	Detailed evaluation of data showed a valid basis for long-term binding of pollutants by biosolids components
	(3) Whether ecological risks, especially phytotoxicity, were properly assessed	Reviewed and explained EPA procedures for ecological risk assessment; specifically described how risks to animals, plants (phytotoxicity), and microbes were determined; policy decision to add ceiling concentration limits to prevent worst-case exposure, partly in response to phytotoxicity concerns (see Step N-6 in text); made plans for additional future ecological and biosolids metal binding studies
	(4) Allow use of PSRP and PFRP	Policy decision to use both; made vector attraction reduction a separate requirement; added monitoring requirement to preclude regrowth for Class A PFRP
	(5) Non-agricultural and surface disposal pollutant limits	Changed from 98th percentile to risk-based limits

(Continued)

Table 9 (Continued)

Issue Raised During	Issue	Resolution of Issue
<i>Step N</i> Internal EPA review (cont.)	(6) Ceiling concentration limits for land application and caps for pollutant concentration limits	Policy decision to use 99th percentile as a ceiling concentration if less stringent than risk-based cumulative pollutant loading rate; used NSSS to assess impact on 1% (99th percentile) of POTWs for final rule (vs. 10%, or 98th percentile, in initial proposed rule); 99th percentile still limits use or disposal of biosolids with highest concentrations of metals
	(7) Assign fraction of ground-water nitrate MCL (10 mg NO ₃ -N) to biosolids nitrogen	Policy decision not to fractionate but to assign entire 10 mg NO ₃ -N to biosolids; no other EPA rule had fractionated the MCL for nitrogen, and no agreed upon basis for fractionization has been established
	(8) Use biosolids as model for nutrient management	Policy decision—too complex an issue for unilateral decision by EPA; involves all sources of nutrients from chemical fertilizer, animal manure, and other wastes, as well as biosolids
<i>Step P</i> Comments, lawsuits, EPA revisions	(1) USDA issues, e.g., cadmium ceiling concentration limit; APLR approach	Considering whether to make changes or develop guidances
	(2) Regulation of chromium and molybdenum	Science basis questioned—need for more definitive data; land application pollutant limits for molybdenum deleted except for Part 503 Table 1 ceiling concentration limits
	(3) THC-CO monitoring	Allow either CO or THC monitoring for biosolids incinerators
<i>Step Q</i> Court remand of specific provisions of rule	(1) Chromium land application	Considering deleting chromium as a regulated metal for land application because the risk assessment did not show chromium to be a risk
	(2) 99th-percentile caps for selenium and chromium	Considering deleting chromium from the rule and changing the capped selenium pollutant concentration limit from 36 mg/kg (99th-percentile, policy-based) to 100 mg/kg (risk-based)
	(3) Special land application pollutant limits for heat-dried biosolids	At the time this document was prepared, no final decision had been made
	(4) Different ceiling concentration limits for selenium	At the time this document was prepared, no final decision had been made

Step J-1 Who Is at Risk? The “Highly” Versus “Most Exposed” Individual

Proposed Rule: For the proposed rule EPA focused its risk assessments on the **most exposed individual** (MEI) as the **target organism** (the individual at risk) to be protected from pollutants in biosolids. The MEI was defined as the individual that is most exposed to a pollutant in biosolids for a lifetime (e.g., 70 years, if the MEI was an adult person; or the critical life period of a plant or animal). Worst-case

estimates of the potential for exposure were assigned to the MEI, resulting in very stringent pollutant limits in the proposed rule.

As discussed in Chapter 2, experts were critical of the risk assessments EPA used as a basis for developing the proposed Part 503 rule's pollutant limits. They criticized the use of the MEI as the target organism to be protected, the very conservative assumptions, and the overly stringent models. Some reviewers showed that the use of the MEI was so unrealistic that such an individual would not exist; hence, an assessment of risk to a nonexistent organism would not be meaningful. For example, the MEI used in developing the proposed Part 503 rule for exposure Pathway 1F (exposure Pathway 2 in the final rule's risk assessment) was a hypothetical home gardener:

- Who for 70 years produced essentially all of his or her own food grown in a home garden amended with biosolids.
- Whose biosolids-amended garden soil contained the maximum cumulative permitted application of each of the evaluated pollutants for that 70-year period.
- Whose food harvested from the garden had the highest plant uptake rate for the 70-year period for each of the pollutants, as calculated using data from salt and pot studies.
- Who consumed foods grown in that garden for 70 years (the gardener's food consumption represented both male and female diets simultaneously, and the gardener was always at the age and physiological state for maximum ingestion for each of the food groups [e.g., pregnant, an infant, and a teen-age male]).

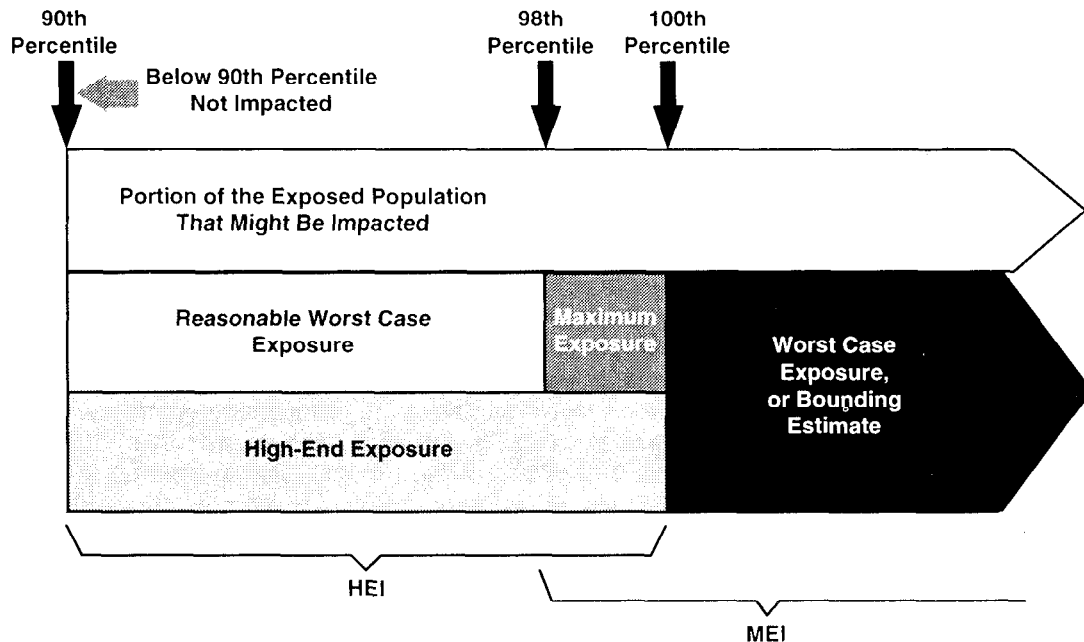
This MEI is illustrated in Figure 3. Because of the highly unlikely combination of all these conservative assumptions, this MEI very likely represents the **worst case** exposure (Ryan and Chaney, 1993).

Final Rule: Because of the many difficulties experienced with the MEI approach, EPA developed a new paradigm for conducting risk assessments (Habicht, 1992). This paradigm, which was used to conduct the risk assessments for the final Part 503 rule, involved the protection of a **highly exposed individual** (HEI) and the use of a combination of high-end and mid-range assumptions in models and algorithms. The HEI also is depicted in Figure 3. In contrast to the MEI, EPA considers the HEI to be more representative of that subset of the population of actual individuals at higher risk than the general population because the HEI models an individual who has high exposure and can exist. Contrast the data, models, and assumptions used for protecting the highly exposed home gardener (Pathway 2) during the revised risk assessments and development of the final Part 503 rule with those previously described for the most exposed home gardener (Pathway 1F). In the revised risk assessment:

- For 70 years, the home gardener HEI produced up to 59 percent of his or her own food (depending on the food group) grown in a home garden amended with biosolids.
- The biosolids-amended garden soil contained the maximum cumulative permitted application of each of the evaluated pollutants for the 70-year period.
- The food harvested from the garden had plant uptake slopes for biosolids pollutants determined using the geometric mean of relevant data from field studies with both acid and neutral biosolids-amended soils.
- Food consumption was apportioned among several different age groups during the 70-year life of the HEI gardener.

Figure 3

Comparisons of the Highly Exposed Individual (HEI) and the Most Exposed Individual (MEI)
(adapted from U.S. EPA, 1991)



Step J-2 Cancer Risk Level Used

Risks from cancer are typically expressed as a "cancer risk level," such as 1×10^{-4} (meaning that the chance of getting cancer is 1 in 10,000) or 1×10^{-6} (meaning that the chance of getting cancer is 1 in 1 million). This number indicates the probability that one additional cancer case (over and above the background cancer risk in individuals not exposed to the pollutant source being evaluated) could be expected to occur in a population of a certain size exposed for 70 years. This level is not a scientific estimate of actual risk but a criterion designed to guide choices among regulatory alternatives. It is an estimate of the upper limits of actual risk that could exist given certain assumptions; the actual risk level is likely to be significantly less than the estimated cancer risk level, and may be zero.

Proposed Rule: EPA's initial biosolids risk assessments conducted for the proposed Part 503 rule evaluated cancer risks associated with pollutants in biosolids at risk levels of 1×10^{-4} (1 cancer case in a population of 10,000 MEIs), 1×10^{-5} (1 cancer case in a population of 100,000 MEIs), and 1×10^{-6} (1 cancer case in a population of 1,000,000 MEIs). The pollutant limits in the proposed Part 503 rule were based on risk levels of 1×10^{-4} for all use or disposal practices except incineration, which was proposed to be regulated at 1×10^{-5} because the aggregate (population) risk assessment indicated that incineration posed a higher risk than other use or disposal practices.

Final Rule: Cancer risks were reevaluated in the revised risk assessments conducted for the final Part 503 rule based on new information obtained after the initial risk assessments were conducted. The new results indicated that minimal risk exists from all current biosolids use or disposal practices, including incineration. Thus, EPA made a policy decision to regulate risks for all biosolids use or disposal practices in the final Part 503 rule at 1×10^{-4} . This risk level is the lifetime cancer risk to a highly exposed individual. EPA believes that a 1×10^{-4} risk level for cancer

risks from pollutants in biosolids provides adequate protection of human health because the latest analyses did not indicate a significant carcinogenic risk to the population as a whole for any biosolids use or disposal practice. EPA estimated that biosolids use or disposal practices prior to promulgation of the final Part 503 rule could have contributed 0.9 to 5 cancer cases annually and that the rule reduces cancer cases by 0.09 to 0.7 annually (see also the questions and answers on this subject in Chapter 6.)

Step J-3 Plant Uptake of Metals: Pot/Salt Vs. Field Studies

Pot/Salt Studies Overestimate Risk

Proposed Rule: For the initial risk assessments conducted for the proposed rule, EPA relied primarily on the results of greenhouse studies in which soluble metal salts were added to soil in pots, rather than on the results of studies conducted in fields, to determine plant uptake of pollutants and phytotoxicity from pollutants in biosolids. This approach was taken in part based on the assumption that it was necessary to obtain adverse effect levels associated with uptake, otherwise the data would not be suitable for use in the risk assessment. In many cases such adverse effects data were found only in pot/salt studies and not in pot/biosolids or field/biosolids studies. Many of the field studies showed no adverse effects because of the binding of pollutants by components of the biosolids matrix. (See photographs on facing page.)

Final Rule: Careful evaluation of the data and new research conducted since the initial Part 503 risk assessments indicated that the results of metal salt and pot studies greatly overestimated phytotoxicity and the bioavailability of pollutants in biosolids (USDA/CSRS, 1989). This is because certain components in biosolids (e.g., ferric hydrous oxides, organic matter, phosphates) bind pollutants to the biosolids, making the pollutants less available to plants, animals, and humans (Corey et al., 1987; Chaney and Ryan, 1994; Mahler et al., 1987). This biosolids binding effect is not present when pure metal salts (rather than metals in biosolids) are added to soil. In addition, conditions of pot studies (e.g., plant root confinement, elevated soil temperature, rapidly changing water environment due to evaporation and transpiration) tend to increase the uptake of pollutants by plants compared to uptake under field conditions.

Plant Response to Metals

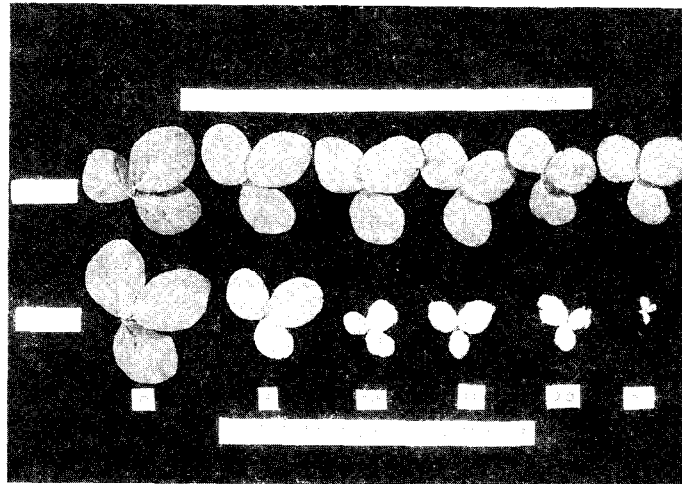
The differences between plant uptake of metals in field soils amended with biosolids versus plant uptake of metal salts added to soils in pots or in the field is also illustrated in Figure 4. When pure metal salts are added to soils, a **linear response** occurs (i.e., as the concentration of metal salts increases in the soil, the concentration of metal increases in plants). This is because the added metal salts are not bound as tightly by the soil as are metals in biosolids-amended soils (see description below) and therefore are taken up more freely by plant roots.

In contrast, a **plateau response** in plant uptake occurs when plants are grown in soil-biosolids mixtures (see Figure 4). This plateau response has been observed repeatedly in numerous field studies. With the plateau effect, the rate of pollutant uptake by plants in the soil-biosolids mixture decreases with increased biosolids-metal loadings (Chaney et al., 1982). The plateau effect occurs because the adsorptive materials in the biosolids become as important or more important than the adsorptive materials initially in the soil. Hence, the uptake slope for the pollutant levels off because more of the stronger biosolids adsorptive capacity is added for each unit of the pollutant that is added. More specifically, when soils are first amended with initial amounts of biosolids, which generally contain low levels of metals, plants and soils compete for the biosolids-bound metals and uptake of

1



2



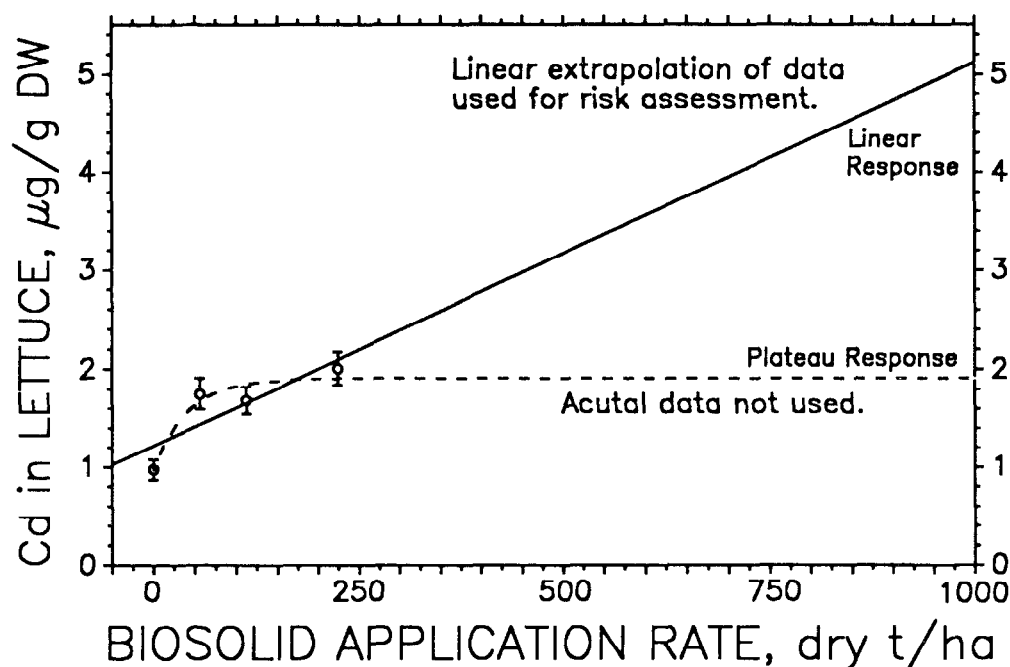
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(Photographs by Rufus Chaney, USDA)

Plants respond very differently in pot studies vs. field studies. Photograph 1 shows plants grown in pot studies. The plant on the left was grown in low pH soil; the plant on the right was grown at pH 6.5. Photograph 2 is a close-up of leaves taken from the plants shown in Photograph 1, with the low pH leaves shown at the bottom. Photograph 3 shows plants thriving in the field, even though they are being grown in low pH soil. Documented field study research and operational experience were used in the biosolids risk assessment for land application for the final Part 503 rule whenever possible because these data are much more representative of real-world conditions.

Figure 4
Comparisons of the Plateau and Linear Plant Uptake Responses to Metals



(Adapted from Chaney, 1993)

metals may increase in plants (e.g., uptake appears to be linear). As more biosolids are added to the soil, the strong binding sites of the biosolids matrix become dominant over the weaker binding sites in the soil. Consequently, phytoavailability (the ability of plants to take up metals) no longer increases with further additions of biosolids, resulting in the plateauing effect. For some elements, interactions between several pollutants also hinder uptake by plants (e.g., zinc inhibits cadmium uptake).

Nevertheless, EPA continued to use the conservative linear response assumption for land application Pathways 1, 2, 4, 6, and 8 in the risk assessment for the final Part 503 rule, even though it significantly overestimates pollutant uptake by plants. Plateau regression could not be fully estimated because data were not available from field studies using different rates of application over many years. Hence, linear response was retained in the final rule. This conservative assumption of linearity was used in combination with less conservative assumptions, such as using the geometric mean (rather than the more conservative arithmetic mean) from a large number of studies to determine input values used in calculating plant uptake slopes, as described below.

Calculating Plant Uptake Slopes

Prior to calculating plant uptake slopes for pollutants in the revised risk assessment, EPA reviewed, corrected, expanded, and ranked the data from numerous studies on plant uptake (see Box 4).

Data from Type A (field) studies were used whenever available for the revised risk assessment because they best represent conditions being regulated. Nonetheless, for certain categories of studies other types of data were used. Data from Type B biosolids pot studies were used for mercury and selenium. Type C data were used for arsenic for all but "leafy vegetables," for which Type A data were used.

Box 4

EPA Plant Uptake Data Ranking Classification

- Type A:* Data from studies conducted in fields where biosolids had been applied.
- Type B:* Data from all other studies conducted with biosolids (i.e., field studies using biosolids spiked with additional metals; greenhouse studies using plants grown in biosolids in pots).
- Type C:* Data from all other non-biosolids metals studies in the field or greenhouse (e.g., studies using metal salts or soils contaminated or geochemically enriched from sources other than biosolids).

The plant uptake slope, or response, for each study was then calculated. For studies with multiple application rates and tissue concentrations, the linear regression statistical method was used to calculate the plant uptake slope. For studies with one metal application rate and one plant tissue concentration, the uptake slope was calculated as shown in Box 5.

If the calculated uptake slope was negative or zero, a default slope of 0.001 was used. It is quite reasonable that the uptake slope of metals may be negative (i.e., that lower amounts of metals are obtained from soil by plants after biosolids are added to soils, even though the biosolids also contain the same metals). A negative slope would result from the strong binding surfaces in the biosolids matrix, which hold metals already present in soils and reduce their availability for plant uptake. The use of a minimum plant uptake slope was required for calculating geometric means. Therefore, the conservative assumption of a 0.001 minimum uptake slope allowed negative uptake data to be included in the risk assessment data set, even though that assumption caused the uptake slopes for the pollutants analyzed to be overestimated and the pollutant limits to be conservative.

Plant types were assigned to food groups (garden fruits, grains and cereals, leafy vegetables, legumes, potatoes, and root vegetables), and the uptake slope for each food group was calculated for each pollutant using the geometric mean ("average") of the uptake slopes already calculated for individual studies in the food group. Box 6 provides an example calculation.

Box 5

Sample Plant Uptake Calculation for a Study With One Observation

Algorithm:

$$\text{Plant Uptake (UC)} = \frac{\text{Tissue Concentration } (\mu\text{g-pollutant/g-plant tissue, DW})}{\text{Metal Application Rate (kg-pollutant/hectare of land, DW)}}$$

Variables (for cadmium, swiss chard, pH 6.2 [Chaney and Hornick, 1978; CAST, 1980]):

$$\text{Tissue Concentration} = 1.675 \text{ } (\mu\text{g/g DW})$$

$$\text{Metal Application Rate} = 4.43 \text{ (kg/ha)}$$

Calculation:

$$UC = \frac{1.675}{4.43} = 0.378 \text{ } (\mu\text{g/g DW})(\text{kg/ha})^{-1}$$

Box 6

Sample Plant Uptake Slope Calculation for a Food Group

Algorithm:

$$(UC_1 \cdot UC_2 \cdot \dots \cdot UC_n)^{-n} = \text{geometric mean of slopes, where:}$$

UC_n = plant uptake slope calculated in Study 1, 2, etc.
for a plant species

Variables (hypothetical):

	Study 1	Study 2	Study 3
UC	0.005	0.023	0.005

Calculation:

$$(0.005 \cdot 0.023 \cdot 0.005)^{-3} = 0.0185 (\mu\text{g-pollutant/g-plant tissue DW})(\text{kg-pollutant/hectare of land DW})^{-1}$$

Step J-4 Food Consumption

The assumptions used in the biosolids risk assessments regarding the amounts of food from different types of food groups that people consume influenced risk calculations in important ways.

Proposed Rule: For the land application risk assessment conducted for the proposed Part 503 rule, EPA used conservative dietary data to determine human exposure to pollutants in biosolids through food consumption. The risk assessment used the highest daily consumption rate of each of eight food groups (e.g., consumption of dairy products by teen-age males, consumption of leafy vegetables by adult females, milk fat consumption of infants for polychlorinated biphenyl [PCB] uptake). These assumption rates were used to calculate risks to people from consuming plants grown on soils to which biosolids were land applied or animal products from animals that had consumed such plants.

Further evaluation showed that such an approach resulted in an unrealistic “megaeater”—a person who is always of the age and physiological state for maximum ingestion of the pollutant (e.g., simultaneously pregnant, an infant, and a teen-age male, who ingests maximum rates for an entire 70-year life span). Such an approach would have overestimated exposure through dietary consumption by 3- to 10-fold.

Final Rule: EPA used an updated methodology and new data to calculate human dietary exposure to pollutants in biosolids for the final Part 503 rule (see Appendix B). This approach involved the derivation of more realistic values for dietary exposure by apportioning food consumption among several different age periods during the 70-year life of the HEI. Consistent with the new EPA paradigm for risk assessment, this less conservative but more realistic approach to assessing dietary intake was combined with both mid-range values (e.g., geometric mean of pollutant concentrations in food) and high-end, more conservative assumptions (e.g., regarding pollutant toxicity and linearity of pollutant uptake by plants) in calculations used to determine pollutant loading limits.

Step J-5 Pollutants Deleted

Organic Pollutants

Biosolids are known to contain synthetic organic chemicals (e.g., PCBs and polycyclic aromatic hydrocarbons [PAHs]).

Proposed Rule: Comments on the proposed Part 503 rule included recommendations that some of the organic pollutants proposed for regulation be deleted because the pollutants are either banned or restricted for use in the United States.

Final Rule: In response, EPA decided to reevaluate all organic pollutants proposed for regulation in the Part 503 rule. The results of this evaluation, as well as numerous research studies and the National Sewage Sludge Survey (NSSS), showed that organic pollutants occurred in biosolids in the United States at low levels that do not pose significant risks to public health or the environment. Thus, EPA decided to delete regulation of organic pollutants in the final Part 503 rule because organic pollutants met at least one of the following three criteria:

- The pollutant has been banned or restricted for use in the United States, or is no longer manufactured for use in the United States.
- The pollutant is not present in biosolids at significant frequencies of detection (i.e., 5 percent) based on data gathered in the NSSS in biosolids.
- The limit for the pollutant identified in the biosolids risk assessments is not expected to be exceeded in biosolids that are used or disposed, based on data from the NSSS.

The limits that might have been used based on the risk assessments if the organic chemical pollutants were included in the rule are listed in Table 11 (in Chapter 4).

Inorganic Pollutants

Final Rule: For surface disposal sites without a liner and leachate collection system, in addition to organics, the inorganics cadmium, copper, lead, mercury, and chromium met one of the three criteria discussed above (i.e., were not expected to exceed the levels identified in the risk assessment). Thus, EPA determined that risks from these inorganics in surface-disposed biosolids were negligible. The Agency believed that meeting these criteria protected human health and the environment from reasonably anticipated adverse effects of these pollutants in biosolids without establishing pollutant limits for them in the Part 503 rule. All pollutants, both inorganic and organic, were deleted from Part 503 regulation for surface disposal sites with a liner and leachate collection system based on the assumption that any potential migration of pollutants to ground or surface water would be precluded.

Step L Inclusion of "Pollutant Concentration Limits" (for Low-Metal Biosolids) for Land Application in the Part 503 Rule

Experts who assisted EPA in revising the biosolids risk assessments and the proposed Part 503 rule recommended including a provision that would identify biosolids containing low levels of pollutants which could be used with minimal regulatory oversight. These experts proposed levels of pollutants that, based on the risk assessment and data from field investigations, showed very low risk from land application of biosolids, even when soils were poorly managed. After reviewing these recommendations, along with results of the NSSS, which showed that pollutant levels in biosolids had dropped, EPA proposed the concept for comment. Known as the "clean" biosolids concept, this provision was adopted as part of the final Part 503 rule as "pollutant concentration limits."

Research conducted over the past decade (Chaney, 1993; Chaney and Ryan, 1991, 1993; Chang et al., 1992; Korcak and Fanning, 1985; USDA/CSRS, 1989) has clearly demonstrated that biosolids with low levels of pollutants, such as those designated by the Part 503 pollutant concentration limits, are associated with no observed adverse effects in the field. Thus, these biosolids are also known as “no observed adverse effect level (NOAEL)” biosolids. Chapter 5 discusses how the pollutant concentration limits for NOAEL biosolids were determined.

Part 503 allows NOAEL biosolids to be used with minimal regulatory oversight (i.e., additional cumulative amounts of pollutants added to land are not required to be tracked). In addition, if certain pathogen and vector attraction reduction requirements also are met, these biosolids do not have to meet Part 503 general requirements and management practices for land application. These simplified land application provisions provide an incentive to biosolids generators to improve the quality of biosolids and recycle them. EPA's ***A Plain English Guide to the EPA Part 503 Biosolids Rule*** (U.S. EPA, 1994) provides additional details on these provisions.

Step N-1 Risk From Exposure to Lead in Land-Applied Biosolids

Prior to Internal EPA Review: The critical exposure pathway for lead was Pathway 3—children ingesting biosolids that contain lead. Experts assisting EPA with the Part 503 rule initially recommended a lead limit of 300 milligrams per kilogram (mg/kg). This level was determined based on observations of absorbed and retained lead in the bodies of cows, sheep, pigs, and chickens whose diets consisted of up to 10 percent biosolids. In these studies, body burdens of lead (i.e., the content of lead in blood and bone) did not increase unless the lead concentration of biosolids fed as part of the animals' diet exceeded 300 mg/kg. It should be pointed out that if there is no increase in the blood and bone tissue, there can be no increase in any meat or milk from the ingesting animal. Hence, not only are the ingesting animals protected; individuals who might consume the meat or milk from these animals are also protected.

After Internal EPA Review: Prior to promulgation of the final Part 503 rule, there was an extended period during which an internal Agency review took place. EPA reviewers argued that the Agency should be using the ***Integrated Exposure Uptake Biokinetic*** (IEUBK) model to estimate soil/biosolids lead concentration limits that would protect against potential risks to children who ingest biosolids-amended soils. The IEUBK model is used by EPA's Office of Research and Development (ORD) to calculate protective limits against lead risks. The IEUBK model, as used for this calculation, assumed that:

- The lead blood level did not exceed 7.0 micrograms of lead per deciliter of blood (10 micrograms of lead per deciliter is the current critical level that should not be exceeded).
- The portion of the lead that is bioavailable is 60 percent as high as lead absorbed by children if they were to ingest lead from soluble lead salt sources.
- The percentage of the population that could exceed the designated blood level was 5 percent.

Using these IEUBK values, EPA calculated an allowable lead concentration in biosolids of 500 parts per million (ppm). EPA made a conservative policy decision to use the lower of the two sets of lead data—300 ppm—as the pollutant concentration limit in the final Part 503 regulation, thus providing an additional margin of safety for growing children. Studies on rats fed biosolids that contained up to 300 ppm lead per kilogram of biosolids as part of their diet (about 10 percent) have shown that the bioavailability of the biosolids-bound lead is only 5 percent as com-

pared with the 60 percent bioavailability assumed in the IEUBK model calculations. This 12-fold overestimation of the actual bioavailability adds even more conservatism to the calculated pollutant limit.

Step N-2 “Biosolids Binding” of Pollutants: Biosolids Decrease Pollutant Phytoavailability and Bioavailability

Biosolids Binding Is Long Lasting and Reduces Risk

As previously discussed in this chapter, certain components in biosolids (e.g., iron, manganese, and aluminum oxides; organic matter; and phosphates) cause pollutants to be tightly adsorbed to the biosolids, making them less available to plants, animals, and people. This binding property of biosolids is a key reason why research studies have revealed no adverse effects when biosolids containing low levels of pollutants are land applied. Also, risks associated with phytotoxicity and bioavailability of pollutants in biosolids are relatively low when biosolids are land applied at rates commonly used in agriculture and good management practices are followed (Chaney and Ryan, 1993). For example, phytotoxicity from metals in biosolids has not occurred when biosolids have been applied to neutral, alkaline, or acidic soils in accordance with the conditions now required by the Part 503 rule. Phytotoxicity has only occurred when biosolids with high metals concentrations were land applied at high rates or when very low soil pH existed (below 5.0, near 4.5). The nutrient imbalance and phytotoxicity resulting from these two extreme conditions is readily revealed when soils are limed. These conditions are discussed later in this chapter in the section on “Ecological Risks”.

A number of studies have shown that the binding properties of biosolids are environmentally stable (long term). Research has shown that biosolids continue binding metals after being added to soils and that the persistence of binding continues in the field for decades after biosolids addition ceases, even when the organic matter added to the soil with the biosolids decreases. This persistence of the increased metal-binding capacity of biosolids-amended soils also has been determined by studies of soils amended with biosolids over long periods that were collected from farmers' fields and laboratory and greenhouse studies of control soils (the same soils not amended with biosolids) (as discussed in Chaney and Ryan, 1993).

First-Year Biosolids Field Data Overestimate Risk

Not only is the binding of metals in biosolids stable, but binding increases and plant uptake of pollutants decreases over time following the last biosolids application. The highest uptake slope often occurs in the first year after biosolids application. This slope is artificially high during the first year because of metal solubilization, which results from anaerobic biodegradation byproducts and salts associated with the freshly applied biosolids (Chang et al., 1987). Thus, using first-year or short-term data on plant uptake overestimates long-term plant uptake responses. The biosolids risk assessments used long-term plant uptake data when available. Most field studies of biosolids, however, were conducted over a short period (i.e., 5 years or less) and thus the risk assessments yielded estimates of plant uptake that are somewhat conservative.

Additional Conditions That Reduce Risk

Soil-Plant Barrier: The soil-plant barrier concept (described by Chaney, 1980) indicates that plants and/or animals are protected against toxicity from biosolids-applied metals by natural processes in soils, plants, and animals. At least two different protective mechanisms are involved:

- First, some metals are so insoluble or so strongly adsorbed in biosolids-amended soil (e.g., chromium) or plant roots (e.g., lead) that they are not transferred into edible plant parts even when their concentrations are greatly increased in the biosolids/soil mixture.
- Second, when soils are strongly acidic (below pH 5.5) and when the available metal concentration is high, metals such as copper and nickel can be taken up by plants at levels that can cause phytotoxicity, in addition to the metal cadmium, which may cause harm to animals if ingested in sufficient quantity. The edible parts of these plants would be very stunted (small), or the plants would exhibit visible symptoms of phytotoxicity from high levels of metals. As a result, the quantities of such plants, and plant consumption by animals, would be reduced.

Biosolids Elemental Balance Protectiveness: Under some conditions, the soil-plant barrier protection described above does not apply (i.e., risks from excessive selenium, molybdenum, and cadmium in soils would not be prevented by the soil-plant barrier). If present in sufficient quantity in soils, these metals can be taken up by plants at high levels that do not cause toxicity to plants (if available levels of other potentially phytotoxic metals are not excessively high). Metals such as selenium, molybdenum, and cadmium are, however, potentially toxic to animals ingesting the plants if the level of these metals is sufficiently high. Fortunately, another kind of protection is available to the ingesting animals. This protection arises from the significant levels of other substances commonly found in biosolids, such as zinc, calcium, and iron. These substances are taken up by the plant along with metals such as cadmium. Zinc, calcium, and iron are beneficial to the ingesting animal and provide protection by inhibiting absorption of selenium, molybdenum, and cadmium from the ingested food into the animal's intestines and blood stream (see Box 7).

Step N-3 Ecological Risk Assessment

EPA evaluated ecological risks (potential adverse effects on plants and animals) in its risk assessment for land application of biosolids. The risk assessment used the best available ecological data from the scientific literature. Where data were extensive (e.g., on the phytotoxicity of agricultural crops), a comprehensive risk assessment was possible. Where data were more limited, such as for small wildlife and non-agricultural plants in an unmanaged environment, a much more limited approach had to be used for estimating ecological risk. Another difficulty encountered was that currently there is no universally approved procedure for assessing ecological risks.

The general approach followed in conducting the ecological risk assessment for biosolids is outlined below.

Risks to Animals

For animals, risks were evaluated for:

- Agricultural livestock ingesting crops grown on biosolids-amended soil.
- Small herbivores (e.g., deer mice) that live their entire lives in a biosolids-amended area feeding on seeds and small plants close to the biosolids/soil layer in fields, forests, and public contact sites (e.g., parks).
- Animals grazing on forages grown on biosolids-amended forest land or reclamation sites.
- Animals ingesting biosolids (i.e., soil) directly while grazing.
- Soil organisms (e.g., earthworms) living in and consuming biosolids-amended soil.

Box 7

How Diet Alters the Bioavailability of Cadmium: Experience in Japan, the United States, and New Zealand

Rice Grown in Japan

Cadmium in soil and food has been a concern since 1969 when subsistence farmers in the Jinzu Valley, Japan, experienced adverse health effects from consuming rice containing high levels of cadmium (Cd). Women in these farm families developed *itai itai* (or osteomalacia), a painful bone disease, following exposure to excessive cadmium from rice grown in paddies contaminated with mining wastes (10 µg-Cd/g-soil). These families also experienced renal tubular dysfunction (Fanconi syndrome), a disease in which low molecular weight proteins are excreted in urine because of accumulation of cadmium in the kidney cortex. Scientists now know that several circumstances contributed to these health effects:

- *The properties of rice*—The bioavailability of cadmium depends on the presence of calcium, iron, and zinc (Zn) in the rice, which when present are known to interfere with (reduce) cadmium absorption in the human intestine. Milling of brown rice into white rice removes most of these elements but little of the cadmium, thus increasing the bioavailability of cadmium in rice.
- *The diet of the Jinzu Valley farm families*—Malnutrition among the farm families during the pre-war depression, the World War II period, and the post-war depression resulted in a low intake of iron, zinc, and calcium. In addition, the water in Japan is low in calcium. These dietary factors also contributed to increased cadmium absorption from the rice consumed.
- *Properties of flooded soils in rice paddies*—Although the soil in the Jinzu Valley rice paddies was high in zinc (1,200 µg-Cd/g-soil), the cadmium in the soil was more easily oxidized and more soluble than the zinc when the flooded soil was drained. The cadmium was translocated to rice grain at high levels, while zinc remained in the soil or leaves.

Crops in Western Diets

In contrast, Western diets more often consist of substantial quantities of wheat and lettuce, which are grown in non-flooded soils, and rice that is not consumed on a subsistence basis and generally comes from many sources. Zinc always accompanies the cadmium into the edible parts of crops such as wheat and lettuce, reducing absorption of cadmium in the intestine. Usually zinc concentrations are 100 times higher than cadmium levels. Therefore, scientists consider the rice exposure cases in Japan to have no relevance for biosolids risk assessments for Western diets.

This conclusion is borne out by experience in New Zealand, where families fished for and consumed large amounts of cadmium-rich oysters, ingesting a level of cadmium (250 µg Cd/day) similar to that ingested by the farm families in Japan who developed kidney disease. But because neither oysters nor the New Zealand diet were deficient in zinc, iron, or calcium, the New Zealand families experienced no adverse health effects from cadmium ingestion. They did not develop renal tubular dysfunction or accumulate high amounts of cadmium in their kidneys, as did the Jinzu Valley farm families.

Several studies of cadmium in vegetables also demonstrate the low risk from increased cadmium concentration in crops. Morgan and Simms (1988) evaluated a mining site in the United Kingdom where garden soil cadmium levels reached 360 mg Cd/kg dry weight, resulting in cadmium concentrations in vegetables 15 to 60 times higher than in those grown in ordinary soil. This study and others, such as a study by Strehlow and Barltrop (1988) in Shiphams, England, found no evidence of adverse health effects in the population consuming these vegetables. The Ca:Zn ratio was 1:200 at the mining site gardens in Shiphams, England. Similar findings of no increased cadmium-induced kidney dysfunction were found for soils containing 100 mg Cd/kg at a zinc smelter in Palmerton, Pennsylvania. This community included elderly residents who had ingested homegrown garden vegetables over long periods (ATSDR, 1994). The Ca:Zn ratio was 1:100. Also, Chaney and Ryan (1994) found that only if soil cadmium levels exceeded 100 mg Cd/kg dry weight would exposure represent a potential risk to the subsistence Western gardener, based on data from a zinc smelter site. However, since the site was also contaminated with up to 10,000 mg Zn/kg, the zinc prevented the production of high cadmium crops.

Crops Grown in Biosolids-Amended Soils

Soils amended with biosolids that may contain cadmium also may contain zinc (usually at a 1:100 ratio of Cd:Zn by weight), iron, and calcium. When an animal ingests plants grown in such biosolids-amended soils, the animal obtains sufficient quantities of zinc, iron, and calcium along with the cadmium so that the absorption of cadmium is reduced in the animal's intestine. This contrasts with the high absorption of cadmium in the intestine due to diets low in zinc, iron, and calcium, such as the rice-based subsistence Japanese diets described above.

- Animals that eat soil organisms living in biosolids-amended soil (i.e., soil organism predators). Animals that eat earthworms are more highly exposed to potential risks from pollutants in soils than animals that only ingest soils because earthworms bioconcentrate pollutants like cadmium and PCBs. The initial risk assessment, conducted for the proposed rule, identified ducks eating earthworms as a key ecological target organism to be protected (i.e., the MEI); in fact, however, ducks eat grain, aquatic vegetation, and fish rather than earthworms. This was corrected in the revised risk assessment for the final Part 503 rule, which identifies shrews eating earthworms (which had assimilated and bioconcentrated PCBs) as one of the highly exposed key ecological organisms to be protected (i.e., the ecological HEI).

Other important factors in the ecological risk assessment conducted for animals included:

- The rate at which animals accumulate pollutants in their organs from consuming plants grown on biosolids land application sites.
- The maximum intake of a pollutant that would not cause a toxic effect to a most sensitive/most exposed animal; or, alternatively, determination of threshold contaminant concentrations in organs.
- The fraction of the animal diet that is biosolids or plants grown on biosolids-amended sites.
- “Bioavailability” and “bioaccumulation” factors to account for: (1) the ability of animals (particularly earthworms) to accumulate pollutants from soils; (2) the potential for animals (particularly predators of earthworms) to accumulate pollutants from other animals lower in the food chain; and (3) the binding of pollutants within the biosolids/soil mixture, which makes the pollutant less available to plants and animals (see also earlier discussions in this chapter regarding biosolids binding).

Risks to Plants (Phytotoxicity)

Pathway 8 in the biosolids land application risk assessment involves the exposure of plants to pollutants in biosolids added to soils. Adverse effects of these pollutants on plant growth and development are known as **phytotoxic** effects. EPA used a comprehensive approach to establish pollutant limits that would protect plants from the potentially phytotoxic metals in biosolids (zinc, copper, nickel, and chromium). Alternative procedures were used to establish these limits, and the procedure yielding the most stringent limit for a given metal was chosen as the pollutant limit for Pathway 8, the phytotoxicity pathway.

First Procedure for Determining Plant Metal Concentrations That Characterize Phytotoxicity (the Probability Approach)

Step 1: EPA searched the literature to identify plant tissue concentrations of metals associated with amount of growth. In the experiments analyzed, different species of plants were grown in nutrient solution or pots of soil with and without additions of different test metal salts for 2- to 6-week periods. The studies determined the concentrations of different metals in the vegetative tissues of various plant species associated with 8, 10, 25, and 50 percent retardation of vegetative growth, measured as shoot growth. The leaf concentration associated with **50 percent growth reduction** was selected as the phytotoxicity threshold (PT₅₀) for use in the risk assessment for the phytotoxicity pathway.

The PT₅₀ was used because EPA determined that relatively severe initial effects (50 percent or greater growth reductions) would be necessary to correspond to later yield reductions, given that short-term growth effects do not necessarily translate into longer term yield reductions at maturity (the actual criterion used to define

phytotoxicity). Exceeding the phytotoxicity threshold 1 out of every 100 times was considered acceptable. Even if the Agency had chosen a **25 percent reduction in growth** (PT_{25}) as the phytotoxicity threshold, the maximum loading rate (i.e., that would not exceed the threshold leaf concentrations) would not have been meaningfully different from that calculated using the PT_{50} . For example, at PT_{25} for zinc, the probability that this threshold would be exceeded at a 3,500 kilograms per hectare (kg/ha) loading rate would be 0.0011. This probability is equivalent to 1.1 chances in 1,000 (much less than 1 in 100). The probability of exceeding the PT_{50} at this same loading rate of 3,500 kg/ha would be <0.0001, or 0.1 chance in 1,000 (again much less than 1 in 100), as shown in Chart C of Box 10 (in Chapter 4). Thus, the results using PT_{25} and PT_{50} thresholds are not meaningfully different: 3,500 kg/ha would be the maximum loading rate for zinc determined using the probability approach under either threshold assumption. It is important to note that detection of significant growth reduction in the field (across seasons for any crop) of less than 25 percent—from any cause—is very difficult.

Step 2: Next, EPA used data from biosolids field experiments in which corn or soybeans had been grown. Because EPA had previously determined that uptake of metals by plants grown on biosolids-amended soils in the field cannot be simulated by plants grown in pots (see “Pot/Salt Studies Overestimate Risk,” earlier in this chapter), EPA limited uptake data strictly to that obtained from field studies. EPA calculated geometric means and standard deviations of metal concentrations in plant tissues corresponding to various soil metal loadings. These data were then used to determine probabilities of reaching the PT_{50} for each metal in each plant species. **Corn** was selected as the focus of the analysis because more field data were available for corn than for any other plant species. A value of 0.01 was selected as an acceptable level of tolerable risk for exceeding the PT_{50} (i.e., exceeding the PT_{50} 1 out of every 100 times was considered acceptable). The probabilities of the pollutants in field-grown corn meeting or exceeding the PT_{50} threshold were significantly less than 0.01 at all biosolids loading rates analyzed, the highest of which were 3,500 kg/ha for zinc and 1,500 kg/ha for copper. An example of how the probabilities were used to select the limit for zinc is shown in Chapter 4, Box 10 (see Approach 1 and Chart C).

For chromium and nickel, the probabilities that these metal concentrations in corn leaf would exceed their PT_{50} s decreased as the cumulative loadings increased. This might be caused by dilution or by reactions of other biosolids constituents with chromium and nickel, rendering these metals less bioavailable. Because plant yields in field experiments did not show any negative effects from biosolids application (i.e., in all cases, there was no yield suppression, and in many cases yields increased), it is probable that phytotoxicity does not occur from chromium or nickel. Based on maximum loadings used in the evaluated scientific research, EPA determined that 3,000 kg/ha chromium and 420 kg/ha nickel can be safely applied without affecting corn yields.

Second Procedure for Determining Plant Metal Concentrations That Characterize Phytotoxicity (the Calculation Approach)

A problem inherent in the Probability Approach discussed above is that corn is not very sensitive to phytotoxicity from metals; thus, a second procedure also was used to characterize phytotoxicity. In EPA's second procedure, plant tissue concentrations associated with yield reduction were obtained from the literature to define an upper bound on phytotoxic effects for sensitive plant species (e.g., **lettuce**). Sensitive plant species are more susceptible than corn to metal-induced inhibition of growth (phytotoxicity). These data were used to develop plant tissue levels of metals associated with **first detectable yield reductions**. These concentrations were identified as the phytotoxicity threshold for each of four metals.

More specifically, using a linear response slope assumption (which is highly conservative given the plateau response actually seen for biosolids—see “Plant Response to Metals,” earlier in this chapter), EPA calculated the geometric and arithmetic means for plant response to each metal, which were used to calculate the metal loading projected to result in plant tissue concentration associated with the first detectable yield reduction. The average of these geometric and arithmetic means were individually calculated for each metal as cumulative load applications in kg/ha (the phytotoxicity thresholds) (see Chapter 4, Box 10, Approach 2).

Selection of the Most Conservative Loading Rate From the First and Second Approaches as the Phytotoxicity Limit

For zinc, a mean of 2,800 kg/ha was calculated as the loading rate using the second procedure described above (the Calculation Approach; also see Chapter 4, Box 10), which was compared to the value determined using the Probability Approach (first procedure, described above). A limit was never actually reached for zinc using the Probability Approach (i.e., no phytotoxicity was observed even at the highest loading rate, so the highest loading rate analyzed, 3,500 kg/ha, was identified as a “limit”). The 2,800 kg/ha value identified by the Calculation Approach was within the upper loading range (2,500-3,500 kg/ha) of the Probability Approach, and thus 2,800 kg/ha, the more conservative rate, was chosen as an appropriate pollutant loading rate for zinc.

For copper, a mean of 2,500 kg/ha was calculated as the pollutant loading rate using the Calculation Approach, which was compared to the value identified in the Probability Approach (cumulative loading rates up to 1,500 kg/ha). The more conservative of these two values—the 1,500 kg/ha—was chosen as the appropriate limit for copper.

Similarly, for nickel, a limit of 2,400 kg/ha was calculated using the Calculation Approach as compared to 420 kg/ha for the Probability Approach. The more conservative value of the two, 420 kg/ha, was chosen as an appropriate limit for nickel.

Finally, for chromium, a limit could not be identified using the Calculation Approach. Thus, the maximum loading rate used in any experiment using the Probability Approach, 3,000 kg/ha, was used as an appropriate limit for chromium even though no yield reduction was observed using this procedure either. It should be noted that chromium will likely be dropped from the Part 503 rule due to the lack of adverse effects and a recent court action (see also the discussions on chromium in Steps P and Q of this chapter).

Holistic Review of Field Data To Determine If Phytotoxicity Limits Were Protective

A comprehensive review was made of plant metal concentration data and yields from all available biosolids field studies (U.S. EPA, 1992a), including all data reflecting various soil types and biosolids sources. This review found no instances of phytotoxicity concentration limits being exceeded nor yield reductions, even in crops that tend to accumulate metals and exhibit phytotoxicity symptoms, such as Swiss chard, lettuce, and soybeans, unless the biosolids contained very high concentrations of metals (above Part 503 ceiling concentrations) or the plants were grown in soils at very low pH.

The studies where phytotoxicity did occur were considered atypical because of abnormally high metal concentrations in the biosolids or very low soil pH. These high-metal biosolids can no longer be land applied due to pretreatment standards and/or because they are excluded from being land applied by the ceiling concentration limits in the Part 503 rule. In addition, the agricultural use of soils with low pHs (below 5.5) is unlikely because normal agronomic practice calls for maintain-

ing soils above pH 6.0 to prevent the solubilization of naturally occurring metals in soil, such as aluminum and manganese; these metals can have a significant toxic effect on plants (whether or not biosolids are used). Hence, data from these atypical field studies were not used in developing the final phytotoxicity pollutant limits.

Risks to Soil Microbes?

Most studies have shown no adverse effects on soil microbial activity associated with metals in biosolids or soil (including nitrification and mineralization of nitrogen, as well as normal development and functioning of nitrogen-fixing bacteria for legumes, other than white clover). In one study, however, on land known as the Woburn experimental plots in England, a strain of *Rhizobium* lost its ability to fix nitrogen on one strain of white clover. This loss in ability was noted after a 19-year period of biosolids application with moderately high concentrations of metals (e.g., 100 mg Cd/kg biosolids and 3,000 mg Zn/kg biosolids) to sandy soil on which vegetable crops were being grown. (Nitrogen-fixing microbes are important in agriculture and the environment. They have the unique capability, while in symbiosis in nodules on the plant root, of converting nitrogen gas from the air into organic nitrogen, rather than requiring the plant to absorb fertilizer nitrogen from the soil. The organisms live on the root in irregular, rounded, lump-shaped growths with mutual benefit to both the microbes and plant.)

At the Woburn experimental plots, biosolids were applied from 1942 to 1961. The unique circumstances of the field plots and the findings are as follows:

- No legumes have been seeded into the plots since the initial year of biosolids application, and no new soil microorganisms had been deliberately introduced to the plots for over 20 years after the last application of biosolids.
- Researchers have studied the different species of crops that have grown on these plots long after cultivation of vegetable crops and additions of biosolids ceased, and they have found:
 - One strain of naturally occurring *Rhizobium* on one strain of white clover and one strain of blue-green algae were not capable of fixing nitrogen.
 - Regarding the strain of *Rhizobium* affected, no phytotoxicity occurred to the white clover if nitrogen fertilizer was added.
 - If the plots were inoculated with *Rhizobium leguminosarum* biovar *trifoli* (an effective strain of *Rhizobium* that can form nodules with a group of plant species that includes white and red clover and *Phaseolus* beans, among others), normal nodule formation and fixation of nitrogen occurred (McGrath et al., 1988).
 - After inoculation, effective strains of *Rhizobium* persisted in the soils, at least as long as clover was regularly grown on the soil (Angle et al., 1993).
- Strains of white clover *Rhizobium* on the Woburn plots are considerably more sensitive to zinc and cadmium than United States strains studied under similar conditions (Angle et al., cited in Chaney and Ryan, 1993).

Several studies have found effective strains of white clover *Rhizobium* in farm fields rich in metals. One such study involved soils near a zinc smelter in Pennsylvania, where zinc and cadmium levels in the soil were much higher than in the Woburn study (Angle and Chaney, 1988; Angle et al., in Chaney and Ryan, 1993). Another similar study was reported by Obbard and Jones (1993).

Other research on mine spoils with high levels of metals, analogous to free metal salts in soil, has shown that nitrogen fixation was inhibited in free-living bacteria (Rother et al., 1982), but not by white clover *Rhizobium* until metals levels were so high that phytotoxicity to white clover plants was observed. For all the above rea-

sons, EPA concluded that it was not appropriate to use data from the Woburn study to limit metal applications for the Part 503 rule.

A new study (Ibekwe et al., 1995) provides strong evidence that biosolids were not the cause of *Rhizobium* becoming ineffective on the Woburn plots. Instead, researchers determined that low soil pH caused selection of ineffective strains of *Rhizobium* in both experimental controls (soils without biosolids added) and biosolids-amended soils.

Additional Ecological Monitoring Research

As noted earlier in this section, ecological data are limited. Moreover, at the time the Part 503 risk assessments were conducted, EPA did not have an Agency-wide approved procedure for conducting comprehensive ecological risk assessment. As a result, the biosolids risk assessments did not examine effects on species populations or communities; however, EPA did use the best available data on toxicity to wildlife and plants from pollutants in biosolids in its ecological risk assessment. In so doing, EPA evaluated risks to the most sensitive or most exposed species for which such toxicological data existed. EPA believes that its approach of using only toxicity and uptake data for the *same* sensitive species was both appropriate and protective of the environment. EPA did not believe that it was appropriate to apply pollutant toxicity data obtained for one highly sensitive species to another unrelated species in situations where exposure and uptake or ingestion was known to be very high but the pollutant toxicity data were unknown.

As is always the case with limited data sets, additional experimental data would be desirable. To improve its ability to consider ecological risk from land application of biosolids in the future, EPA has committed itself to conducting and supporting work by others on the ecological impacts of biosolids use. EPA also is working on the further development of a methodology that can gain widespread approval for use in conducting full ecological risk assessments. Biosolids-related ecological research on which EPA will be focusing includes:

- Validation of ground-water models
- Validation of surface-water runoff models
- Further investigation of the nature and ability of biosolids matrices to bind metal pollutants
- Further review of the procedures for determining phytotoxicity
- Further evaluation of ecosystem impacts resulting from the land application of biosolids

Step N-4 Allow Use of PSRP and PFRP for Regulating Pathogens

The regulation of pathogens (e.g., disease-causing organisms such as bacteria and enteric viruses) in the final Part 503 rule is not based on a risk assessment because methodologies had not been developed sufficiently to make such calculations. Instead, the Part 503 pathogen operational standard, which is non-risk based, includes pathogen controls and monitoring requirements for all biosolids, and crop-harvesting, animal grazing, and site-access restrictions for certain biosolids. This operational standard was based on extensive experimental data and years of experience and, in the judgment of EPA, is protective of public health and the environment.

Proposed Rule: For the proposed rule, EPA recommended extensive monitoring of pathogens using one of several different monitoring alternatives. The proposed rule did not permit the use of the older, established processes prescribed in EPA's

Part 257 rule to significantly reduce pathogens (PSRP) or to further reduce pathogens (PFRP).

Final Rule: The final rule permits a combination of monitoring requirements and PSRP and PFRP approaches for controlling pathogen densities in biosolids. The Part 503 rule is different from the Part 257 rule in that it contains separate requirements for pathogen reduction and vector attraction reduction. A more complete description of the requirements for controlling pathogens and vector attraction may be found in *A Plain English Guide to the EPA Part 503 Biosolids Rule* (U.S. EPA, 1994) and *Control of Pathogens and Vector Attraction in Sewage Sludge (Including Domestic Septage) Under 40 CFR Part 503* (U.S. EPA, 1992d).

Step N-5 Regulation of Non-Agricultural Land Application of Biosolids

Proposed Rule: To protect public health and the environment from pollutants in biosolids at non-agricultural land application sites (e.g., forests, reclaimed lands, public contact sites) or at surface disposal sites, EPA proposed a policy-based approach in which pollutant limits were set so that they did not exceed the 98th-percentile concentration of pollutants found in the "40 Cities Study" (see Chapter 2). This approach was recommended because low risk to humans and domestic livestock was expected, given that exposure to pollutants in biosolids at such sites was negligible and pollutant concentrations were found to be low in most biosolids. This approach also was proposed because a risk assessment methodology for such sites did not exist.

Commentors reacted critically to the proposed 98th-percentile approach. They acknowledged that on a simplistic level the 98th-percentile limit would only result in elimination of 2 percent of biosolids from non-agricultural land application or surface disposal. The commentors pointed out, however, that it often was a different 2 percent (of the 26 pollutants proposed for regulation in biosolids) that would be eliminated from use or disposal by this non-risk-based approach, and as many as 52 percent of biosolids could theoretically be eliminated from land application (see Box 8).

Final Rule: The 98th-percentile approach for regulating non-agricultural application and surface disposal was dropped from the final rule because of the difficulties described above. In addition, refined modeling techniques had been developed that the Agency used to conduct formal risk assessments for non-agricultural land application and surface disposal. Hence, in the final Part 503 rule, pollutant limits for non-agricultural land and surface disposal were risk based.

Prior to establishing the final Part 503 risk-based limits for land application of biosolids, the risk-based limits for non-agricultural and agricultural land application were compared and found not appreciably different. Hence, EPA decided to simplify the final rule by using only one set of limits for both types of land application. EPA selected the most stringent of the non-agricultural or agricultural land application limits for each pathway, on which the Part 503 pollutant limits were based regardless of whether the land is being used for agricultural or non-agricultural purposes.

Step N-6 Ceiling Concentration Limits and Caps on Pollutant Concentration Limits

Ceiling Concentration Limits Set After ORD Review

ORD raised an important issue during its final review of the Part 503 rule prior to promulgation regarding the representativeness of the selected plant uptake data. ORD's concern arose because data from experiments involving the use of

Box 8

Potential Impact of a 98th-Percentile Approach on a Biosolids Data Set

- A hypothetical data set contains 100 biosolids and 26 regulated pollutants.
- If there was only one regulated pollutant in the data set of 100 biosolids, then the two biosolids with the highest concentrations of that pollutant would be prohibited from being applied to non-agricultural land or surface disposed, based on the 98th-percentile approach. (It should be pointed out that this prohibition would be imposed regardless of whether those levels were high enough to pose a risk to public health or the environment.)
- Theoretically, if there were 10 regulated pollutants, 20 different biosolids could be prohibited from being applied to non-agricultural land or surface disposed.
- With 26 regulated pollutants, 52 different biosolids could be prohibited from being applied to non-agricultural land or surface disposed using this approach.
- An evaluation of a Michigan data set containing analyses of over 200 biosolids samples revealed that nearly 40 percent of the biosolids from POTWs in that data set would have been prohibited from being applied to non-agricultural land or surface disposed if non-risk-based 98th-percentile concentration limits were the final pollutant limits in the Part 503 rule.

Thus, the 98th-percentile approach was dropped. Part 503 pollutant limits for non-agricultural land application and surface disposal were based on risk assessments.

biosolids with high pollutant concentrations were not included in the data set. EPA did not include these data because they were viewed as nonrepresentative (i.e., uptake of pollutants from high-pollutant concentration biosolids is more like uptake from metal salt and pot studies, discussed earlier in this chapter). To overcome the potential problems associated with phytotoxicity data from soils amended with biosolids containing high pollutant levels or from metal pot/salt studies, a policy decision was made to establish 99th-percentile **ceiling concentration limits**. These ceiling limits preclude land application of biosolids if any of the regulated pollutant concentrations in the biosolids are greater than the 99th percentile of the pollutant concentrations in the NSSS or the calculated risk-based pollutant concentrations, whichever is the least stringent (also see Chapter 5).

Caps: A Risk Management Decision

EPA also chose to include **caps** (as pollutant concentration limits for land application, discussed earlier in this chapter and in Chapter 5) at levels that were previously calculated as permissible by the risk assessment. The pollutant concentrations calculated by the risk assessment were compared with the 99th-percentile pollutant concentrations in the NSSS. If the 99th-percentile concentration was more stringent than the pollutant concentration identified by the risk assessment, as was the case for chromium and selenium, then the 99th-percentile number was used to cap (reduce) the calculated risk-based concentration and became the concentration limit for that pollutant. If the risk assessment limit was more stringent than the NSSS level, the risk assessment number was used as the pollutant concentration limit. For chromium and selenium, these determinations will likely be moot because of court determinations described in Steps P and Q of this chapter.

Additional Discussion

The ceiling concentration limits and the caps on pollutant concentration limits in biosolids in the Part 503 rule provide an additional margin of safety. The ceilings and caps also help ensure that the quality of current biosolids is maintained. The



Corn grown without biosolids (left), compared with corn grown in biosolids-amended soil (right).

decision to use the 99th-percentile ceiling limits and caps was a policy decision, although (as described above) the use of these limits ensures that the biosolids being used have pollutant concentrations consistent with the biosolids field data used for the risk assessment. EPA chose the 99th-percentile rather than the 98th-percentile limits for caps and ceiling limits for the final rule to reduce the impact on wastewater treatment facilities. If ceiling limits and caps had been set at the 98th percentile of the NSSS data, a significantly greater percentage of biosolids generated in the United States would have been precluded from land application (see Box 8). Because neither percentile is risk-based, the less restrictive 99th-percentile limit was chosen. Other means of encouraging the further reduction of metal content in biosolids include the reduced Part 503 regulatory requirements for biosolids meeting pollutant concentration limits and Class A pathogen requirements; guidance provided to biosolids generators; and the continued emphasis on pretreatment and source reduction. As stated above, the determinations pertaining to caps will likely be moot because of court determinations described in Steps P and Q below.

EPA believes that the 99th-percentile approach is appropriate for ceiling concentration limits, given that it prohibits the most contaminated biosolids (which act more

like metal salts) from being land applied. This approach supports the selection of data from biosolids field experiments used for the risk assessment, which did not include biosolids with the highest metal content and also did not include metal pot/salt studies.

Step N-7 Protection of Ground Water From Excess Nitrogen

Ground water is protected from biosolids with nitrogen levels in excess of estimated crop needs by the Part 503 rule's requirement that biosolids be land applied at the agronomic rate. Ground water also is protected by Part 503's requirement that nitrate-nitrogen be monitored at biosolids surface disposal sites.

Some commentors on the biosolids rule proposed assigning a fraction of the nitrate-nitrogen Maximum Contaminant Level (MCL) for ground water (which is 10 ppm) to biosolids that are used or disposed. EPA found no basis for such an assignment. Therefore, as EPA does for all pollutant sources of nitrate-nitrogen, the Agency assigned the entire 10-ppm MCL for nitrate-nitrogen content in ground water to biosolids. The Agency agreed to review this decision based on further analysis at a later time.

Step N-8 Management and Regulation of Nutrients

The Part 503 requirement for the application of biosolids at the agronomic rate appropriate for the yield and crop being grown is consistent with sound management of the nutrient nitrogen. Although EPA considered using the Part 503 rule as part of an overall nutrient management model (i.e., for regulating the application of a number of nutrients from various sources), the Agency made a policy decision not to address this complex issue in the Part 503 rule. Many other sources of nutrients would need to be involved in a nutrient management program (e.g., chemical fertilizers, animal manures, other wastes), which EPA does not have the authority to regulate under the Clean Water Act. Moreover, EPA believes that other agencies and knowledgeable parties should be involved in developing such a program. In addition, EPA felt that biosolids should not be singled out from other nutrient sources, particularly because biosolids tend to pose less of a public health and environmental risk due to lower nutrient levels in biosolids than many other sources and because currently no EPA nutrient requirements address these other sources of nutrients.

Step P USDA Comments, EPA Revisions

Issues regarding the final, promulgated Part 503 rule were raised by a number of outside commentors. Some of the issues and recommendations by the U.S. Department of Agriculture (USDA) are presented below to illustrate the interaction between risk assessment and risk management in establishing the Part 503 pollutant limits.

Cadmium: USDA recommended that the ceiling concentration limit for cadmium in biosolids land applied to soils be limited to 21 mg-Cd/kg-soil, dry-weight basis, rather than the current Part 503 limit of 39 mg Cd/kg.

USDA noted that certain European Union (EU) and other potential international markets for U.S. grains and sunflower kernels have established very low cadmium concentration limits for imported grains, even though no risk has been identified from ingestion of grains with such low cadmium levels in careful scientific research. Hence, grains produced in the United States with cadmium contents in excess of the imposed standards of other countries could not be exported to those countries. USDA agrees that grain produced on soils amended with biosolids containing 39 mg Cd/kg does not pose a risk (unless the cadmium to zinc ratio is much higher than normal levels [<0.0145]). Nonetheless, because of these international market

restrictions, USDA has recommended lowering the cadmium limit. USDA suggests that a 21 mg Cd/kg limit would be relatively easy to attain given that 91 percent of U.S. wastewater treatment facilities that generate biosolids could meet this limit (based on data from the NSSS).

USDA pointed out that exporting grains containing cadmium is already a problem because some regions of the United States currently cannot meet the EU limits due to naturally occurring levels of cadmium in soils. In addition, certain crop species accumulate higher cadmium levels in their grain than do other crops. USDA is concerned that use of biosolids containing levels of cadmium as high as 39 mg/kg (particularly on acidic soils, which may result in plants taking up more cadmium) could further exacerbate current exportation problems by causing the production of even more grains with cadmium levels above the EU limits.

Changing the limit from 39 mg Cd/kg could be problematic because, as discussed in the next section (see “Provisions of the Rule Remanded by the Court”), the court challenged EPA’s use of non-risk-based means for setting certain limits. USDA and EPA are planning to issue guidance on this issue.

Molybdenum: USDA also recommended that EPA reduce the ceiling concentration limit for molybdenum (Mo) in biosolids to 54 mg Mo/kg, the 98th percentile in the NSSS. This recommendation was made because some of the field studies from which plant uptake slopes for molybdenum for sensitive crop species were calculated did not involve alkaline soil pH. USDA was concerned that because molybdenum uptake is much greater at pH 8 than at pH 7, an HEI ruminant animal might not be protected from biosolids with higher concentrations of molybdenum applied to alkaline soils.

EPA deleted all requirements from the Part 503 rule for molybdenum except the ceiling concentration limits as a result of the February 25, 1995, amendment, pending careful additional study and consideration of new data (see Chapter 2). No final decision on establishing new pollutant limits for the deleted molybdenum limits had been reached by EPA at the time of this document’s preparation. EPA does not expect to change the existing ceiling concentration limit for molybdenum.

98th Instead of 99th Percentile as a Cap on Pollutant Concentration Limits: USDA believes that lowering the cap on pollutant concentration limits for additional protection (from the current 99th percentile to the 98th percentile, as was previously proposed by EPA) would be a prudent policy decision.

The recent remand by the court that would preclude EPA’s use of policy-based 99th-percentile NSSS concentration limits as caps to pollutant concentration limits would suggest that use of 98th-percentile NSSS concentration limits as caps would not be possible (see Step Q below on court remands).

Annual Pollutant Loading Rate Limits: USDA recommended that annual pollutant loading rate (APLR) limits should be deleted from the final Part 503 rule. USDA pointed out the limited usefulness of the APLR approach for regulating the use of biosolids in bags or containers, which was originally devised prior to the development of the “pollutant concentration limit” approach (discussed earlier in this chapter and in Chapter 5). USDA recommends deleting the APLR approach because its use would allow distribution to the public of biosolids containing higher levels of pollutants than the pollutant concentration limit approach.

EPA believes that the likelihood of the APLR approach being used has greatly diminished now that the pollutant concentration limit approach has been adopted in the final rule. The Agency has made no decision about whether to drop the APLR approach from the rule at the time of this document’s preparation.

Chromium: USDA has recommended that chromium limits be deleted from the Part 503 rule because there is no evidence of damage to plants or animals from the levels of chromium currently found in biosolids. The court remanded the chromium limits to EPA for modification or additional justification.

EPA plans to delete all chromium limits for land-applied biosolids from the Part 503 rule. An important reason for imposition of the chromium limits by EPA was a policy-based desire to reduce levels of chromium in wastewater effluents and biosolids via pretreatment.

Soil pH: USDA recommended that EPA reconsider its decision not to impose soil pH requirements in the Part 503 rule for biosolids that contain an insufficient lime equivalent to neutralize the acidity generated during oxidation of biosolids in biosolids-amended soils.

EPA has decided not to make this recommended change. (See also the discussion regarding pH earlier in this chapter.)

Selenium: USDA recommended limiting the addition to soil of selenium in biosolids to 28 kg/ha to avoid excessive plant uptake and possible poisoning of certain sensitive livestock or wildlife.

No decision on this issue had been reached by EPA at the time of this document's preparation.

Arsenic: USDA recommended increasing the pollutant concentration limit for arsenic in the Part 503 rule because the conservative policy decision to use a relative effectiveness (RE) value of 1 (i.e., implying that arsenic is highly bioavailable, see Chapter 4) caused the current Part 503 pollutant concentration limit to be much lower than if calculated using experimentally derived RE values (i.e., the bioavailability of biosolids-applied arsenic is much lower than assumed).

EPA has no current plans to change the pollutant concentration limit for arsenic in the Part 503 rule.

Step Q Lawsuits, Provisions of the Rule Remanded by the Court

The provisions of the Part 503 rule remanded to EPA for modification or additional justification by the court are still applicable while EPA studies the remanded issues and decides whether to (1) agree with the court recommendations, (2) justify the provisions, or (3) recommend no or partial change. The remanded provisions are summarized below.

Chromium: The court stated that EPA should drop chromium from the Part 503 rule because the biosolids risk assessment did not identify any chromium level associated with risk to public health or the environment. EPA agrees and plans to delete all chromium limits for land-applied biosolids from the Part 503 rule.

Selenium: In response to the pleadings of a plaintiff that the EPA selenium limits posed a special hardship to certain communities because of naturally occurring high levels of selenium in the area, the court reviewed the various selenium limits in the rule. The court stated that the capped 99th-percentile pollutant concentration limit for selenium was based on a policy decision and should be eliminated. In light of other comments by USDA that the current ceiling limit is too high and may cause a problem for animal life (see preceding section), EPA has a difficult decision to make. If the only basis for lowering the limit is a policy decision, EPA may recommend changing the capped selenium pollutant concentration limit from 36 to 100 mg/kg biosolids.

The court also remanded to EPA the potential for a special provision to allow increased selenium pollutant limits on public contact sites with a low potential for exposure.

Heat-Dried Biosolids: The court remanded to EPA the issue of whether to establish a special provision that would set higher pollutant concentration limits for heat-dried biosolids. The reason for the remand was a plaintiff's pleading that heat-dried biosolids would always be used at low rates and therefore should be allowed higher pollutant concentration limits. Most likely, EPA will not make this change.

Dedicated Beneficial Use of Biosolids: The court asked that EPA consider moving the category of "dedicated beneficial use of biosolids" from the surface disposal to the land application section of the Part 503 rule. A plaintiff argued in his pleading to the court that having dedicated beneficial use of biosolids in the surface disposal section of the Part 503 rule is very detrimental to efforts for gaining public acceptance for using biosolids to improve highly acidic disturbed lands that are also particularly low in organic matter and plant nutrients.

The court agrees that EPA does not need to move the "dedicated beneficial use of biosolids" category from the surface disposal to the land application section of the rule. Moving this category to the land application section of the rule, however, would help encourage beneficial use of biosolids and reclamation of disturbed lands, another important EPA goal. No decision on this issue had been reached by EPA at the time of this document's preparation.